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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

SEPRACOR INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,  
et al.,

Defendants.

**Civil Action No. 2:09-cv-01302-DMC-MF**

**DEFENDANTS WOCKHARDT LTD.'S  
AND WOCKHARDT USA LLC'S  
AMENDED ANSWER AND  
COUNTERCLAIMS**

**(Filed Electronically)**

Defendants Wockhardt Ltd. and Wockhardt USA LLC (collectively, “Wockhardt”), by and through their attorneys, Duane Morris LLP, answer the Amended Complaint of Plaintiff Sepracor Inc. (“Sepracor”) as follows:

**PARTIES**

1.A. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 1.A and therefore denies them.

1.B.-1.D. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.B.-1.D. and therefore denies them.

1.E. Wockhardt admits that Wockhardt Ltd. is an Indian corporation having a principal place of business at Wockhardt Towers, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India. Wockhardt admits that Wockhardt Ltd. has an office in New Jersey and does business in this judicial district. Wockhardt admits that Dr. Brij Khera was a New Jersey employee of Wockhardt Ltd. and was authorized to negotiate access to Wockhardt Ltd.’s confidential information under Wockhardt Ltd.’s Offer of Confidential Access in this action, negotiated the terms of such access, and caused to be sent from New Jersey certain confidential information of Wockhardt Ltd. that is the subject of Sepracor’s claims against Wockhardt Ltd. and Wockhardt USA in this action. Wockhardt denies the remaining allegations of paragraph 1.E.

1.F. Wockhardt admits that Wockhardt USA LLC is a Delaware limited liability company having a place of business at 20 Waterview Boulevard, Parsippany, NJ 07054. Wockhardt admits that Wockhardt USA LLC is an indirect subsidiary of Defendant Wockhardt Ltd. Wockhardt admits that Wockhardt USA LLC is registered to do business in New Jersey and does business in this judicial district.

1.G. Wockhardt admits that certain paragraphs of Sepracor's complaint refer to Wockhardt Ltd. and Wockhardt USA LLC collectively as "Wockhardt." Otherwise denied.

1.H.-1.FF. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraphs 1.H.-1.FF. and therefore denies them.

### **NATURE OF THE ACTION**

2. Paragraph 2 states legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt admits that this action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.* Wockhardt denies the remaining allegations of this paragraph.

### **JURISDICTION AND VENUE**

3. Paragraph 3 states legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt admits that this Court has jurisdiction over the subject matter of this action. Wockhardt does not contest venue in this judicial district for the limited purpose of this action only. Insofar as the allegations of paragraph 3 pertain to other defendants, Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies them.

4. Paragraph 4 states legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt consents to this Court's personal jurisdiction for the purposes of the present litigation only, but denies that it has committed, aided, abetted, contributed to and/or participated in the commission of a tortious act of patent infringement that has led to any foreseeable harm or injury to Sepracor. Insofar as the allegations of paragraph 4 pertain to other defendants, Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies them.

5.-6. Wockhardt is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraphs 5-6 and therefore denies them

7. Paragraph 7 states legal conclusions to which no answer is required. To the extent that an answer is required, Wockhardt consents to personal jurisdiction over Defendant Wockhardt USA LLC for the limited purpose of this litigation only. Wockhardt admits that Wockhardt USA LLC has consented in an email dated March 17, 2009 to personal jurisdiction and venue in this judicial district for the purpose of this litigation.

8. Paragraph 8 states legal conclusions to which no answer is required. To the extent that an answer is required, Wockhardt consents to personal jurisdiction over Defendant Wockhardt Ltd. for the limited purpose of this litigation only. Wockhardt admits that Wockhardt Ltd. has consented in an email dated March 17, 2009 to personal jurisdiction and venue in this judicial district for the purpose of this litigation.

9.-26. Wockhardt is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraphs 9-26 and therefore denies them.

### **THE PATENTS**

27. Wockhardt admits that the '257 patent states on its face an issue date of March 8, 2005, is titled "Optically Active 5H-Pyrrolo[3,4-B] Pyrazine Derivative, Its Preparation and Pharmaceutical Compositions Containing It," and names Sepracor as assignee. Wockhardt admits that a copy of the '257 patent is attached to the Complaint as Exhibit A. Wockhardt is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 27 and therefore denies them.

28. Wockhardt admits that the '673 patent states on its face an issue date of September 3, 2002, is titled "Optically Active 5H-Pyrrolo[3,4-B] Pyrazine Derivative, Its Preparation and Pharmaceutical Compositions Containing It," and names Sepracor as assignee.

Wockhardt admits that a copy of the '673 patent is attached to the Complaint as Exhibit B. Wockhardt denies that the '673 patent was duly and legally issued. Wockhardt is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 28 and therefore denies them.

29. Wockhardt admits that the '926 patent states on its face an issue date of November 20, 2001, is titled "Optically Active 5H-Pyrrolo[3,4-B] Pyrazine Derivative, Its Preparation and Pharmaceutical Compositions Containing It," and names Sepracor as assignee. Wockhardt admits that a copy of the '926 patent is attached to the Complaint as Exhibit C. Wockhardt is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 29 and therefore denies them.

30. Wockhardt admits that the '724 patent states on its face an issue date of June 3, 2008, is titled "Optically Active 5H-Pyrrolo[3,4-B] Pyrazine Derivative, Its Preparation and Pharmaceutical Compositions Containing Same," and names Sepracor as assignee. Wockhardt admits that a copy of the '724 patent is attached to the Complaint as Exhibit D. Wockhardt is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 30 and therefore denies them.

#### **COUNT I - ALLEGED INFRINGEMENT OF THE '257 PATENT BY TEVA**

31. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 30 as if fully set forth herein.

32.-39. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 32-39 and therefore denies them.

**COUNT II - ALLEGED INFRINGEMENT OF THE '257 PATENT BY REDDY**

40. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 39 as if fully set forth herein.

41.-48. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 41-48 and therefore denies them.

**COUNT III - ALLEGED INFRINGEMENT OF THE '257 PATENT BY ROXANE**

49. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 48 as if fully set forth herein.

50.-56. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 50-56 and therefore denies them.

**COUNT IV - ALLEGED INFRINGEMENT OF THE '257 PATENT BY COBALT**

57. Wockhardt incorporates by references its answers to the preceding paragraphs 1 through 56 as if fully set forth herein.

58.-65. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 58-65 and therefore denies them.

**COUNT V - ALLEGED INFRINGEMENT OF THE '257 PATENT BY GLENMARK**

66. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 65 as if fully set forth herein.

67.-74. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 67-74 and therefore denies them.

**COUNT VI - ALLEGED INFRINGEMENT OF THE '257 PATENT BY ORCHID**

75. Wockhardt incorporates by references its answers to the preceding paragraphs 1 through 74 as if fully set forth herein.

76.-83. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 76-83 and therefore denies them.

**COUNT VII - ALLEGED INFRINGEMENT OF THE '257 PATENT BY LUPIN**

84. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 83 as if fully set forth herein.

85.-92. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 85-92 and therefore denies them.

**COUNT VIII - ALLEGED INFRINGEMENT OF THE '257 PATENT BY SUN**

93. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 92 as if fully set forth herein.

94.-101. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 94-101 and therefore denies them.

**COUNT IX - ALLEGED INFRINGEMENT OF THE '257 PATENT BY ALPHAPHARM**

102. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 101 as if fully set forth herein.

103.-110. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 103-110 and therefore denies them.

**COUNT X - ALLEGED INFRINGEMENT OF THE '673 PATENT BY WOCKHARDT**

111. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 110 as if fully set forth herein.

112. Wockhardt admits that it submitted ANDA No. 91-165 to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of eszopiclone oral tablets. Wockhardt admits that ANDA No. 91-165 contains a certification

pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) with respect to the ‘673 patent. Wockhardt admits that ANDA No. 91-165 seeks FDA approval of a generic version of Sepracor’s Lunesta<sup>®</sup> brand 1 mg, 2 mg and 3 mg eszopiclone tablets. Otherwise denied.

113. Wockhardt admits that ANDA No. 91-165 certifies under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that no valid claim of the ‘673 patent will be infringed by the manufacture, use, or sale of the Wockhardt ANDA product. Wockhardt admits that Sepracor received written notification of ANDA No. 91-165 and the § 505(j)(2)(A)(vii)(IV) allegations on February 26, 2009. Otherwise denied.

114. Wockhardt denies the allegations of paragraph 114.

115. Wockhardt denies the allegations of paragraph 115.

116. Wockhardt denies the allegations of paragraph 116.

117. Wockhardt admits that it was aware of the ‘673 patent and of its filing of ANDA No. 91-165 which contained a certification with respect to the ‘673 patent. Wockhardt denies the remaining allegations of paragraph 117.

118. Wockhardt denies the allegations of paragraph 118.

119. Wockhardt denies the allegations of paragraph 119.

#### **COUNT XI - ALLEGED INFRINGEMENT OF THE ‘673 PATENT BY REDDY**

120. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 119 as if fully set forth herein.

121.-128. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 121-128 and therefore denies them.



**COUNT XII - ALLEGED INFRINGEMENT OF THE '673 PATENT BY ROXANE**

129. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 128 as if fully set forth herein.

130.-136. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 130-136 and therefore denies them.

**COUNT XIII - ALLEGED INFRINGEMENT OF THE '673 PATENT BY COBALT**

137. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 136 as if fully set forth herein.

138.-145. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 138-145 and therefore denies them.

**COUNT XIV - ALLEGED INFRINGEMENT OF THE '673 PATENT BY GLENMARK**

146. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 145 as if fully set forth herein.

147.-154. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 147-154 and therefore denies them.

**COUNT XV - ALLEGED INFRINGEMENT OF THE '673 PATENT BY ORCHID**

155. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 154 as if fully set forth herein.

156.-163. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 156-163 and therefore denies them.

**COUNT XVI - ALLEGED INFRINGEMENT OF THE '673 PATENT BY LUPIN**

164. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 163 as if fully set forth herein.

165.-172. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 165-172 and therefore denies them.

**COUNT XVII - ALLEGED INFRINGEMENT OF THE '673 PATENT BY SUN**

173. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 172 as if fully set forth herein.

174.-181. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 174-181 and therefore denies them.

**COUNT XVIII - ALLEGED INFRINGEMENT OF THE '673 PATENT BY ALPHAPHARM**

182. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 181 as if fully set forth herein.

183.-190. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 183-190 and therefore denies them.

**COUNT XIX - ALLEGED INFRINGEMENT OF THE '926 PATENT BY REDDY**

191. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 190 as if fully set forth herein.

192.-199. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 192-199 and therefore denies them.

**COUNT XX - ALLEGED INFRINGEMENT OF THE '926 PATENT BY ROXANE**

200. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 199 as if fully set forth herein.

201.-207. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 201-207 and therefore denies them.

**COUNT XXI - ALLEGED INFRINGEMENT OF THE '926 PATENT BY COBALT**

208. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 207 as if fully set forth herein.

209.-216. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 209-216 and therefore denies them.

**COUNT XXII - ALLEGED INFRINGEMENT OF THE '926 PATENT BY GLENMARK**

217. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 216 as if fully set forth herein.

218.-225. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 218-225 and therefore denies them.

**COUNT XXIII - ALLEGED INFRINGEMENT OF THE '926 PATENT BY ORCHID**

226. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 225 as if fully set forth herein.

227.-234. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 227-234 and therefore denies them.

**COUNT XXIV - ALLEGED INFRINGEMENT OF THE '926 PATENT BY LUPIN**

235. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 234 as if fully set forth herein.

236.-243. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 236-243 and therefore denies them.

**COUNT XXV - ALLEGED INFRINGEMENT OF THE '926 PATENT BY SUN**

244. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 243 as if fully set forth herein.

245.-252. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 245-252 and therefore denies them.

**COUNT XXVI - ALLEGED INFRINGEMENT OF THE '926 PATENT BY ALPHAPHARM**

253. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 252 as if fully set forth herein.

254.-261. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 254-261 and therefore denies them.

**COUNT XXVII - ALLEGED INFRINGEMENT OF THE '724 PATENT BY REDDY**

262. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 261 as if fully set forth herein.

263.-270. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 263-270 and therefore denies them.

**COUNT XXVIII - ALLEGED INFRINGEMENT OF THE '724 PATENT BY ROXANE**

271. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 270 as if fully set forth herein.

272.-277. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 272-277 and therefore denies them.

**COUNT XXIX - ALLEGED INFRINGEMENT OF THE '724 PATENT BY COBALT**

278. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 277 as if fully set forth herein.

279.-286. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 279-286 and therefore denies them.

**COUNT XXX - ALLEGED INFRINGEMENT OF THE '724 PATENT BY GLENMARK**

287. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 286 as if fully set forth herein.

288.-295. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 288-295 and therefore denies them.

**COUNT XXXI - ALLEGED INFRINGEMENT OF THE '724 PATENT BY ORCHID**

296. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 295 as if fully set forth herein.

297.-304. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 297-304 and therefore denies them.

**COUNT XXXII - ALLEGED INFRINGEMENT OF THE '724 PATENT BY LUPIN**

305. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 304 as if fully set forth herein.

306.-313. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 306-313 and therefore denies them.

**COUNT XXXIII - ALLEGED INFRINGEMENT OF THE '724 PATENT BY SUN**

314. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 313 as if fully set forth herein.

315.-322. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 315-322 and therefore denies them.

**COUNT XXXIV - ALLEGED INFRINGEMENT OF THE '724 PATENT BY  
ALPHAPHARM**

323. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 322 as if fully set forth herein.

324.-331. Wockhardt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 324-331 and therefore denies them.

**COUNT XXXV - ALLEGED INFRINGEMENT OF THE '257 PATENT BY  
WOCKHARDT**

332. Wockhardt incorporates by reference its answer to the preceding paragraphs 1 through 331 as if fully set forth herein.

333. Wockhardt admits that it submitted ANDA No. 91-165 to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of eszopiclone oral tablets. Wockhardt admits that ANDA No. 91-165, as amended on or before June 15, 2009, contains a Paragraph IV Certification with respect to the '257 patent. Wockhardt admits that ANDA No. 91-165 seeks FDA approval of a generic version of Sepracor's Lunesta<sup>®</sup> brand 1 mg, 2 mg and 3 mg eszopiclone tablets. Otherwise denied.

334. Wockhardt admits that ANDA No. 91-165 certifies under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that no valid claim of the '257 patent will be infringed by the manufacture, use or sale of the Wockhardt ANDA product. Wockhardt admits that Sepracor received written notification of the amendments to ANDA No. 91-165 and the § 505(j)(2)(A)(vii)(IV) allegations on June 15, 2009.

335. Wockhardt denies the allegations of paragraph 335.

336. Wockhardt denies the allegations of paragraph 336.

337. Wockhardt denies the allegations of paragraph 337.

338. Wockhardt admits that it was aware of the '257 patent and of its filing of ANDA No. 91-165, as amended, which contained a certification with respect to the '257 patent. Wockhardt denies the remaining allegations of paragraph 338.

339. Wockhardt denies the allegations of paragraph 339.

340. Wockhardt denies the allegations of paragraph 340.

**COUNT XXXVI - ALLEGED INFRINGEMENT OF THE '926 PATENT BY WOCKHARDT**

341. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 340 as if fully set forth herein.

342. Wockhardt admits that it submitted ANDA No. 91-165 to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use and sale of eszopiclone oral tablets. Wockhardt admits that ANDA No. 91-165, as amended on or before June 15, 2009, contains a Paragraph IV Certification with respect to the '926 patent. Wockhardt admits that ANDA No. 91-165 seeks FDA approval of a generic version of Sepracor's Lunesta<sup>®</sup> brand 1 mg, 2 mg and 3 mg eszopiclone tablets. Otherwise denied.

343. Wockhardt admits that ANDA No. 91-165, as amended, certifies under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that no valid claim of the '926 patent will be infringed by the manufacture, use or sale of the Wockhardt ANDA product. Wockhardt admits that Sepracor received written notification of the amendments to ANDA No. 91-165 and the § 505(j)(2)(A)(vii)(IV) allegations on June 15, 2009.

344. Wockhardt denies the allegations of paragraph 344.

345. Wockhardt denies the allegations of paragraph 345.

346. Wockhardt denies the allegations of paragraph 346.

347. Wockhardt admits that it was aware of the '926 patent and of its filing of ANDA No. 91-165, as amended, which contained a certification with respect to the '926 patent. Wockhardt denies the remaining allegations of paragraph 347.

348. Wockhardt denies the allegations of paragraph 348.

349. Wockhardt denies the allegations of paragraph 349.

**COUNT XXXVII - ALLEGED INFRINGEMENT OF THE '724 PATENT BY WOCKHARDT**

350. Wockhardt incorporates by reference its answers to the preceding paragraphs 1 through 349 as if fully set forth herein.

351. Wockhardt admits that it submitted ANDA No. 91-165 to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use and sale of eszopiclone oral tablets. Wockhardt admits that ANDA No. 91-165, as amended on or before June 15, 2009, contains a Paragraph IV Certification with respect to the '724 patent. Wockhardt admits that ANDA No. 91-165 seeks FDA approval of a generic version of Sepracor's Lunesta<sup>®</sup> brand 1 mg, 2 mg and 3 mg eszopiclone tablets. Otherwise denied.

352. Wockhardt admits that ANDA No. 91-165, as amended, certifies under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that no valid claim of the '724 patent will be infringed by the manufacture, use or sale of the Wockhardt ANDA product. Wockhardt admits that Sepracor



received written notification of the amendments to ANDA No. 91-165 and the § 505(j)(2)(A)(vii)(IV) allegations on June 15, 2009.

353. Wockhardt denies the allegations of paragraph 353.

354. Wockhardt denies the allegations of paragraph 354.

355. Wockhardt denies the allegations of paragraph 355.

356. Wockhardt admits that it was aware of the '724 patent and of its filing of ANDA No. 90-165, as amended, which contained a certification with respect to the '724 patent. Wockhardt denies the remaining allegations of paragraph 356.

357. Wockhardt denies the allegations of paragraph 357.

358. Wockhardt denies the allegations of paragraph 358.

### **SEPARATE DEFENSES**

#### **FIRST DEFENSE (Invalidity)**

The claims of the '673, '257, '926 and '724 patents are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code, including without limitation, one or more of 35 U.S.C. §§ 101, 102, 103, 112, and/or 120, and/or based on other judicially-created bases for invalidation.

#### **SECOND DEFENSE (Non-infringement)**

The manufacture, use, sale, offer for sale, and/or importation into the United States of eszopiclone oral tablets that are the subject of ANDA No. 91-165 will not infringe, either literally or under the doctrine of equivalents, directly or indirectly, any valid claim of the '673, '257, '926 and '724 patents.

### **THIRD DEFENSE (Unenforceability)**

For at least the reasons outlined in the Counterclaims below, the ‘673, ‘257, ‘926 and ‘724 patents are unenforceable for inequitable conduct before the U.S. Patent and Trademark Office.

### **FOURTH DEFENSE (Additional Defenses)**

Wockhardt reserves all defenses, at law or equity, that may now exist or in the future be available on discovery and further factual investigation in this case.

### **COUNTERCLAIMS**

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Wockhardt by way of its Counterclaims against Sepracor, Inc. (“Sepracor”), alleges as follows:

1. Wockhardt repeats and incorporates by reference each of the foregoing paragraphs of Wockhardt’s Answer and Additional Defenses to the Complaint.

2. This is an action for a declaratory judgment of non-infringement, invalidity, and/or unenforceability of United States Patent Nos. 6,444,673 (“the ‘673 patent”), 6,319,926 (“the ‘926 patent”), 6,863,257 (“the ‘257 patent”) and 7,381,724 (“the ‘724 patent”) under 35 U.S.C. § 271(e)(5), 28 U.S.C. §§ 2201(a) and (b), and/or 21 U.S.C. § 355(j). A true and correct copy of the ‘673 patent is attached hereto as Exhibit A. A true and correct copy of the ‘926 patent is attached hereto as Exhibit B. A true and correct copy of the ‘257 patent is attached hereto as Exhibit C. A true and correct copy of the ‘724 patent is attached hereto as Exhibit D.

### **The Parties**

3. Wockhardt USA, LLC is a limited liability company organized under the laws of the state of Delaware, having a principal place of business at 20 Waterview Boulevard, Parsippany, NJ 07054. Wockhardt Ltd. is an Indian corporation having a principal place of

business at Wockhardt Towers, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

4. On information and belief, Sepracor is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 84 Waterford Drive, Marlborough, MA 01752.

5. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 35 U.S.C. § 271(e)(5); 28 U.S.C. §§ 1331, 1337(a), 1338(a) and (b), 2201(a) and (b), 2202; and/or 21 U.S.C. § 355(j), based on an actual controversy between Wockhardt and Sepracor arising under the Patent Laws of the United States, 35 U.S.C. § 100 et seq.

6. This Court has personal jurisdiction over Sepracor based, *inter alia*, on the filing by Sepracor of this lawsuit in this jurisdiction.

7. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

**Orange Book Listing of the ‘673, ‘926, ‘257 and ‘724 Patents**

8. On information and belief, Sepracor is the assignee of the ‘673, ‘926, ‘257 and ‘724 patents.

9. On information and belief, pursuant to 21 U.S.C. § 355(b)(1)(G), Sepracor caused the FDA to publish the ‘673, ‘926, ‘257 and ‘724 patents in the Orange Book in connection with NDA No. 21-476.

10. By maintaining the listing of the ‘673, ‘926, ‘257 and ‘724 patents in the Orange Book, Sepracor represents that the ‘673, ‘926, ‘257 and ‘724 patents “could reasonably be

asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug.” 21 U.S.C. § 355(b)(1)(G).

### **Wockhardt’s Abbreviated New Drug Application**

11. Wockhardt filed ANDA No. 91-165 (“the Wockhardt ANDA”) with the FDA seeking approval to market its proposed eszopiclone oral tablets in 1 mg, 2 mg, and 3 mg strengths. Wockhardt certified to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (referred to as a “Paragraph IV certification”) and 21 C.F.R. § 314.95, that the ‘673 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale and/or offer for sale of Wockhardt’s proposed eszopiclone tablets. Wockhardt subsequently amended its ANDA with the FDA and provided a Paragraph IV certification that the ‘926, ‘257 and ‘724 patents are also invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale and/or offer for sale of Wockhardt’s proposed eszopiclone tablets.

12. In accordance with the requirements of 21 U.S.C. § 355(j)(2)(B), Wockhardt mailed Sepracor notice letters stating that it had filed ANDA No. 91-165, containing a Paragraph IV certification regarding the ‘673, ‘926, ‘257 and ‘724 patents and offering Sepracor confidential access to ANDA No. 91-165. Sepracor accepted and agreed to an offer of Confidential Access regarding ANDA No. 91-165, and Wockhardt provided Sepracor with information from Wockhardt’s ANDA.

### **The Existence of a Justiciable Controversy**

13. Wockhardt’s Paragraph IV certifications state that the ‘673, ‘926, ‘257 and ‘724 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale and/or offer for sale of Wockhardt’s proposed eszopiclone tablets.

14. In response to Wockhardt's ANDA and Paragraph IV certifications against the '673, '926, '257 and '724 patents, Sepracor filed this infringement action under 35 U.S.C. § 271(e)(2)(A), asserting the '673, '926, '257 and '724 patents, thus gaining the exclusionary benefit of an automatic 30-month stay of approval of Wockhardt's ANDA.

15. Wockhardt has not stipulated to or otherwise consented to the validity, infringement, or enforceability of the '673, '926, '257 and '724 patents.

16. If Wockhardt succeeds in proving that the '673, '926, '257 and '724 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale and/or offer for sale of Wockhardt's proposed eszopiclone tablets, such a judgment will remove any independent barriers to competition that may exist by virtue of Sepracor's maintenance of the listing of the '673, '926, '257 and '724 patents in the Orange Book in connection with NDA No. 21-476.

17. In light of all the circumstances, an actual substantial and continuing justiciable controversy having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Sepracor and Wockhardt as to whether the '673, '926, '257 and '724 patents are invalid, unenforceable and/or not infringed by Wockhardt.

### **FIRST COUNT**

#### **(Declaratory Judgment of Invalidity, United States Patent No. 6,444,673)**

18. Wockhardt repeats and incorporates by reference each of the foregoing paragraphs of Wockhardt's Answer and Defenses to the Complaint and of these Counterclaims.

19. An actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Sepracor and Wockhardt concerning the invalidity of claims of the '673 patent.

20. Claims of the '673 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 et seq., including, without limitation, 35 U.S.C. §§ 101, 102, 103, 112 and/or 120, and/or based on other judicially-created bases for invalidation.

21. Thus, Wockhardt is entitled to a declaratory judgment that claims of the '673 patent are invalid.

### **SECOND COUNT**

#### **(Declaratory Judgment of Non-Infringement, United States Patent No. 6,444,673)**

22. Wockhardt repeats and incorporates by reference each of the foregoing paragraphs of Wockhardt's Answer and Defenses to the Complaint and of these Counterclaims.

23. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Sepracor and Wockhardt concerning the non-infringement of claims of the '673 patent.

24. Wockhardt's manufacture, use, offer for sale, sale and/or importation into the United States of eszopiclone tablets pursuant to ANDA No. 91-165 will not infringe any valid and enforceable claim of the '673 patent.

25. Thus, Wockhardt is entitled to a declaratory judgment that Wockhardt's eszopiclone tablets will not infringe any valid and enforceable claim of the '673 patent.

### **THIRD COUNT**

#### **(Declaratory Judgment of Invalidity, United States Patent No. 6,319,926)**

26. Wockhardt repeats and incorporates by reference each of the foregoing paragraphs of Wockhardt's Answer and Defenses to the Complaint and of these Counterclaims.

27. An actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Sepracor and Wockhardt concerning the invalidity of claims of the '926 patent.

28. Claims of the '926 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 et seq., including, without limitation, 35 U.S.C. §§ 101, 102, 103, 112 and/or 120, and/or based on other judicially-created bases for invalidation.

29. Thus, Wockhardt is entitled to a declaratory judgment that claims of the '926 patent are invalid.

#### **FOURTH COUNT**

##### **(Declaratory Judgment of Non-Infringement, United States Patent No. 6,319,926)**

30. Wockhardt repeats and incorporates by reference each of the foregoing paragraphs of Wockhardt's Answer and Defenses to the Complaint and of these Counterclaims.

31. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Sepracor and Wockhardt concerning the non-infringement of claims of the '926 patent.

32. Wockhardt's manufacture, use, offer for sale, sale and/or importation into the United States of eszopiclone tablets pursuant to ANDA No. 91-165 will not infringe any valid and enforceable claim of the '926 patent.

33. Thus, Wockhardt is entitled to a declaratory judgment that Wockhardt's eszopiclone tablets will not infringe any valid and enforceable claim of the '926 patent.

#### **FIFTH COUNT**

**(Declaratory Judgment of Invalidity, United States Patent No. 6,864,257)**

34. Wockhardt repeats and incorporates by reference each of the foregoing paragraphs of Wockhardt's Answer and Defenses to the Complaint and of these Counterclaims.

35. An actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Sepracor and Wockhardt concerning the invalidity of claims of the '257 patent.

36. Claims of the '257 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 et seq., including, without limitation, 35 U.S.C. §§ 101, 102, 103, 112 and/or 120, and/or based on other judicially-created bases for invalidation.

37. Thus, Wockhardt is entitled to a declaratory judgment that claims of the '257 patent are invalid.

**SIXTH COUNT**

**(Declaratory Judgment of Non-Infringement, United States Patent No. 6,864,257)**

38. Wockhardt repeats and incorporates by reference each of the foregoing paragraphs of Wockhardt's Answer and Defenses to the Complaint and of these Counterclaims.

39. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Sepracor and Wockhardt concerning the non-infringement of claims of the '257 patent.

40. Wockhardt's manufacture, use, offer for sale, sale and/or importation into the United States of eszopiclone tablets pursuant to ANDA No. 91-165 will not infringe any valid and enforceable claim of the '257 patent.



41. Thus, Wockhardt is entitled to a declaratory judgment that Wockhardt's eszopiclone tablets will not infringe any valid and enforceable claim of the '257 patent.

#### **SEVENTH COUNT**

##### **(Declaratory Judgment of Invalidity, United States Patent No. 7,381,724)**

42. Wockhardt repeats and incorporates by reference each of the foregoing paragraphs of Wockhardt's Answer and Defenses to the Complaint and of these Counterclaims.

43. An actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Sepracor and Wockhardt concerning the invalidity of claims of the '724 patent.

44. Claims of the '724 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 et seq., including, without limitation, 35 U.S.C. §§ 101, 102, 103, 112 and/or 120, and/or based on other judicially-created bases for invalidation.

45. Thus, Wockhardt is entitled to a declaratory judgment that claims of the '724 patent are invalid.

#### **EIGHTH COUNT**

##### **(Declaratory Judgment of Non-Infringement, United States Patent No. 7,381,724)**

46. Wockhardt repeats and incorporates by reference each of the foregoing paragraphs of Wockhardt's Answer and Defenses to the Complaint and of these Counterclaims.

47. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Sepracor and Wockhardt concerning the non-infringement of claims of the '724 patent.

48. Wockhardt's manufacture, use, offer for sale, sale and/or importation into the United States of eszopiclone tablets pursuant to ANDA No. 91-165 will not infringe any valid and enforceable claim of the '724 patent.

49. Thus, Wockhardt is entitled to a declaratory judgment that Wockhardt's eszopiclone tablets will not infringe any valid and enforceable claim of the '724 patent.

### **NINTH COUNT**

#### **(Declaration Of Unenforceability of the '673, '926, '257 and '724 Patents)**

50. Wockhardt repeats and incorporates by reference each of the foregoing paragraphs of Wockhardt's Answer and Defenses to the Complaint and of these Counterclaims.

51. As set forth below, Wockhardt is entitled to a declaration that each of the '673 '926, '257 and '724 patents ("the Orange Book patents") is unenforceable due to inequitable conduct in prosecuting the Orange Book patents before the PTO.

#### **Inequitable Conduct**

52. On information and belief, Sepracor, the inventors of the Orange Book patents, and/or other persons substantively involved in prosecuting the Orange Book patents engaged in a pattern of intentionally deceptive conduct throughout the prosecution of the family of applications that resulted in issuance of the Orange Book patents. The conduct was designed to maximize Sepracor's patent protection over its eszopiclone product eventually marketed as Lunesta<sup>®</sup>. Upon information and belief, those substantively involved in prosecuting the family of applications that resulted in issuance of the Orange Book patents participated in this scheme at the direction of, with the knowledge of, and/or on behalf of Sepracor. In addition to the evidentiary support detailed below, further evidentiary support for this allegation is likely to be identified after a reasonable opportunity for further investigation and discovery.

53. On information and belief, in violation of their duty of candor to the PTO, those substantively involved in the prosecution of the family of applications that resulted in issuance of the Orange Book patents intentionally misled the PTO by making material misstatements and misrepresentations in support of patentability.

54. Prosecuting a patent application is an *ex parte* process and, therefore, the law imposes a duty of good faith, candor, and disclosure on everyone associated with prosecuting the application. *See* 37 C.F.R. §1.56; Manual of Patent Examining Procedure (MPEP) § 2000.

55. The duty of good faith, candor, and disclosure requires, *inter alia*, the applicant, his agents, attorneys, and anyone else substantively involved in the prosecution of an application disclose all information material to patentability. *See* § 2001.06 of the MPEP.

56. Information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) it establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or (2) it refutes, or is inconsistent with, a position the applicant takes in: (i) opposing an argument of unpatentability relied on by the Office, or (ii) asserting an argument of patentability. Moreover, information is material to patentability if a reasonable patent examiner would have considered such information important in deciding whether to allow an application.

57. The '673 patent claims a chemical compound, namely the dextrorotatory isomer of zopiclone, and pharmaceutical compositions containing that compound. The '926 patent claims a method for improving sleep quality or time by administering the dextrorotatory isomer of zopiclone, essentially free of its levorotatory isomer, to a human. The '257 patent claims a method of inducing an effect selected from the group consisting of a hypnotic effect, a sedative effect and a tranquilizing effect in a human by administering the dextrorotatory isomer of

eszopiclone, essentially free of its levrorotatory isomer. The '724 patent claims a mixture of isomers of [zopiclone], wherein the mixture has an optical rotation  $[\alpha]_D^{20}$  of 135 +/- 3 when measured at 1.0 g/100 mL in acetone.

58. The named inventors of the Orange Book patents, the individuals who submitted Declarations to the PTO during prosecution of the Orange Book patents, the attorneys and patent professionals at the law firm(s) prosecuting the family of applications that resulted in issuance of the Orange Book patents, Sepracor and/or Rhone-Poulenc Rhorer in-house business, legal and/or technical staff involved in efforts to obtain the Orange Book patents and/or other substantively-involved persons to be identified after further investigation and discovery (collectively "the Orange Book patent applicants") asserted, in the Orange Book patent specifications and during prosecution of the family of applications resulting in issuance of the Orange Book patents, that the claims of the Orange Book patents were patentable because the dextrorotatory isomer of zopiclone (also referred to as eszopiclone, the (+) isomer, or the s-isomer), possessed a surprising and unexpected property. On information and belief, the Orange Book patent applicants made these assertions with knowledge of highly material information which refuted, and was inconsistent with, these assertions, but they never disclosed this highly material information to the PTO.

59. The Orange Book patents make the following assertions regarding the relative toxicity of the isomers of zopiclone:

In a racemic product, it is known that, often, one of the two enantiomers is active and that an enhancement of the toxicity may be linked to this activity, the other enantiomer being both markedly less active or inactive and less toxic. For such products, the gain in activity does not compensate for the drawbacks due to an enhanced toxicity.

In the case of zopiclone, it was found, surprisingly and unexpectedly, not only that the dextrorotatory isomer is

approximately twice as active as the racemate while having a lower toxicity than that of the racemate, but that the laevorotatory isomer is both almost inactive and more toxic than the racemate.

For example, when administered orally to mice, zopiclone possesses a toxicity (LD50 [sic LD50]) in the region of 850 mg/kg, whereas the dextrorotatory isomer has a toxicity in the region of 1.5 g/kg and the laevorotatory isomer possesses an LD50 [sic LD50] of between 300 and 900 mg/kg.

e.g., the '673 patent, column 1, lines 35-52.

60. During prosecution of the Orange Book patents before the PTO, the Orange Book patent applicants submitted data, Declarations from scientific personnel, and attorney argument in support of the purported “surprising and unexpected” discovery that racemic zopiclone was more toxic than eszopiclone. The PTO Examiner relied on this data and argumentation in allowing the claims which eventually issued in the Orange Book patents. On information and belief, the Orange Book patent applicants were in possession of information which contradicted their arguments and data, but they did not disclose the contradictory information to the PTO.

61. The Orange Book patent applicants presented data from a rat toxicity study conducted at a dose of 62.5 mg/kg. *Declaration of Bonnefoi*, Application Serial No. 08/493,945 and *Declaration of Doble*, Application Serial No. 09/124,651. According to the Orange Book patent applicants, at this dosage in rats, racemic zopiclone is more toxic than eszopiclone.

Thus, racemic ZOPICLONE showed a statistically significant decrease in free T4 levels at 62.5 mg/kg/day, a dose four times lower than the dose at which a statistically significant decrease occurred for d-ZOPICLONE. Accordingly, it is clear that d-ZOPICLONE has a significantly lower toxicity than racemic ZOPICLONE.

*Amendment After Final Under 37 C.F.R. § 1.116*, November 17, 1997, Application Serial No. 08/493,946 at pages 7-8.

62. The Orange Book patent applicants further argued to the PTO that this incredibly high dosage (corresponding to approximately 50 times the recommended dose in humans) corresponds to a drug abuse dosage and is therefore within the “conditions of use” of zopiclone. *Second Preliminary Amendment and Request than an Interference be Declared Under 37 C.F.R. § 1.607*, February 12, 1999.

63. In February 2001, the Orange Book patent applicants filed a Continued Prosecution Application “for the purpose of placing of record several items which are listed in the Information Disclosure Statement (IDS) filed concurrently herewith.” *Preliminary Remarks*, February 5, 2001, Appln. Serial No. 09/124,651 at page 1. Among the items submitted was a one-page summary data sheet form Sepracor’s IND for Lunesta<sup>®</sup> presenting the results of an acute oral toxicity test in mice using racemic zopiclone and its isomers. According to the Orange Book patent applicants,

None of this cited information related to toxicity is believed to adversely affect patentability of the allowed claim, but is brought to the Patent and Trademark Office’s attention out of an abundance of caution in view of prosecution of the parent, in which issues relating to the effects of (+) zopiclone vs. the racemate were considered. In particular, claim 6 was allowed in view of the showing that the (+) zopiclone isomer possesses unexpectedly lower toxicity than the racemate *under conditions of use*. Under the dosages considered, the racemate was found to have significant non-lethal thyrotoxicity, in comparison to the (+) isomer. **In the acute toxicity data submitted herewith, the results were generally comparable for the (+) isomer and the racemate.** However, one of ordinary skill in the art would clearly understand that the results obtained upon administration of the massive and lethal dosages employed in the acute toxicity testing are not in conflict with the test results submitted and discussed in the Bonnefoi and Doble Declarations of record, which, as noted above, were based upon dosages corresponding to expected conditions of use in humans.

*Preliminary Remarks*, February 5, 2001, Appln. Serial No. 09/124,651 at page 2 (*italics in original, underlining added*).

64. On information and belief, the **emphasized** portion of the quote in paragraph 39 above is false. The data in the one-page summary from Sepracor's IND shows that the data presented is not "generally comparable" to the data presented in the parent application. In fact, under the conditions tested, the data in the one-page IND summary shows that the (+) isomer exhibits a lower Median Lethal Dose, and is more toxic, than the racemate – in direct contradiction to the data presented in the parent application (and the Orange Book patent specifications). The Orange Book patent applicants were able to make this false statement without the examiner's knowledge because, although, on information and belief, the Orange Book patent applicants knew the (S)-isomer was the (+) isomer, they did not indicate in the one-page summary which of the (S)- and (R)-isomers was the (+) isomer. The Examiner had no way of knowing from the one-page IND summary that the more toxic (S)-isomer was the (+) isomer.

65. On information and belief, the Orange Book patent applicants were in possession of additional data that contradicted the data presented in the Orange Book patent specifications and the Bonnefoi and Doble Declarations, but did not submit that data to the PTO. The Orange Book patent applications possessed data in rats at dosages below 62.5 mg/kg which contradicted the data relied on for allowance – but they did not disclose the contradictory information to the PTO. On information and belief, during the time the Orange Book patent applicants were prosecuting the family of applications leading to issuance of the Orange Book patents, Sepracor conducted, or caused to be conducted, and completed a study entitled "Acute i.v. tox in Albino rats with zopiclone" ("the 1999 Rat Study"). On information and belief, a report of the study was finalized in February 1999. In the 1999 Rat Study, each of (+)-zopiclone ("eszopiclone" or "the S-isomer"), (-)-zopiclone ("the R-isomer") and racemic-zopiclone ("the RS-" or "the racemate") were administered to rats and the median lethal dose (MLD) determined. According

to the summary of the 1999 Rat Study in Sepracor's NDA for Lunesta<sup>®</sup>, the MLD in male rats was lower (more toxic) for (+)-zopiclone (1-10 mg/kg) than for the racemate (25-50 mg/kg). Pharmacology Review, NDA No. 21-476, pages 30-31 (publicly available FDA Approval Package). These toxic dosages are below the 62.5 mg/kg dosage used in the study presented to the PTO by Bonnefoi, Doble and the Orange Book patent applicants. This information contradicts the arguments and Declarations submitted to the PTO that the (+)-isomer has a lower toxicity than that of the racemate. In fact, this information supports the opposite conclusion, namely that the racemate is less toxic than the (+)-isomer (eszopiclone). The Orange Book patent applicants withheld the 1999 Rat Study from the PTO during prosecution of the Orange Book patents.

66. On information and belief, the Orange Book patent applicants were aware of highly material information that refuted, and was inconsistent with, their assertions of a "surprising and unexpected" result, and intentionally withheld that information from the PTO.

67. Based in part on the 1999 Rat Study and the data in the one-page IND summary, the Overall Toxicology Summary in the Lunesta<sup>®</sup> NDA concludes as follows: "Results from both species showed that the most toxic compound of all three based on mortality is the S-form." Pharmacology Review, Overall Toxicology Summary, NDA No. 21-476, page 28 (publically available FDA Approval Package). The "S-form" referred to in the NDA is eszopiclone, the dextrorotatory isomer of zopiclone and the subject of the claims of the Orange Book patents. The conclusion reached in the NDA directly contradicts the statements in the Orange Book patent specifications, and supports the conclusion that the 1999 Rat Study was highly material to the patentability of the claims of the Orange Book patents.



68. On information and belief, one or more of the Orange Book patent applicants knew that the statements in the Orange Book patent specifications and file history regarding the relative toxicity of the isomers of zopiclone were false and misleading, because they knew the results of the 1999 Rat Study and/or the statements in the NDA.

69. The Orange Book patent applicants' pattern of misleading disclosures, selective disclosures, and/or non-disclosures with respect to highly material information demonstrates an intent to deceive or mislead the PTO. As such, the Orange Book patents are unenforceable and cannot be asserted against Wockhardt. Further evidentiary support for this allegation is likely to be identified after a reasonable opportunity for further investigation and discovery.

#### **PRAYER FOR RELIEF**

WHEREFORE, Wockhardt respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiff/Counterclaim Defendant Sepracor as follows:

A. Declaring that Wockhardt has not and will not infringe any valid claim of the '673, '926, '257 and '724 patents asserted by Sepracor;

B. Declaring that no claim of any of the '673, '926, '257 and '724 patents asserted by Sepracor is valid;

C. Declaring that the '673, '926, '257 and '724 patents are unenforceable;

D. Declaring against Sepracor that this is an exceptional case under 35 U.S.C. § 285 and that Wockhardt is entitled to its reasonable attorneys' fees, costs and expenses that it incurs in defending itself in this action;

E. Enjoining Sepracor and its agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof from threatening or initiating infringement litigation against Wockhardt or its customers, dealers, or suppliers, or any

prospective or present sellers, dealers, distributors, or customers of Wockhardt, or charging them orally or in writing with infringement of the '673, '926, '257 and '724 patents asserted herein against Wockhardt;

- F. Granting Wockhardt judgment in its favor on Sepracor's Complaint; and
- G. Awarding any other such relief as is just and proper.

Respectfully submitted,

Dated: July 20, 2009

/s/Gregory R. Haworth  
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*Attorneys for Defendants Wockhardt Ltd. and  
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**LOCAL CIVIL RULE 11.2 CERTIFICATION**

I hereby certify that the matter in controversy is not the subject of any other action pending in any court, or any pending arbitration or administrative proceeding.

DUANE MORRIS LLP

/s/Gregory R. Haworth

Gregory R. Haworth

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Dated: July 20, 2009